

United States Patent Application

for

Manipulation and Cutting System and Method**Inventors**

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Related Application

[001] This application is related to provisional U.S. Patent Application S.N. 60/444,326, filed 1/31/2003 and having the same inventors and same title as the present application, and which is incorporated herein by reference.

Field of the Invention

[002] The present inventions relate to devices and techniques for manipulation and cutting, and more particularly relate to eccentric rotary mechanisms for the cutting and manipulation and methods therefore.

Background of the Invention

10 [003] A known cutting device is the rotary slicer. Where meat is advanced into a thin blade rotating at relatively high speeds. The cutting action of this device is defined by the high slicing to chopping ratio. The resultant blade velocity vector is nearly normal to the direction of advancement. Webb, US 5,569,285 describes a hand powered circular rotary surgical blade with a concentrically mounted cylindrical depth guard. Mueller, US 5507764, describes a powered rotary scalpel method that is capable of developing a relatively high blade velocity relative to linear hand speed in the direction of cutting.

20 [004] For certain clinical procedures, it is very important to make incisions to a precisely controlled pre-determined depth. Certain known devices and methods can be found that address the need to control depth of cut such as Feldman, US 2,882,598 and Williams, US 4,473,076, which describe a depth limiting foot or ski element used in conjunction with a scalpel. Another known method is Urban, US 5,860,996, that discloses a blade actuating assembly, which permits selective longitudinal linear reciprocal movement of a tissue cutting blade positioned at a distal end of a trocar assembly, from a non-deployed position to a deployed position and back to a non-deployed position. The Urban device moves in a longitudinal motion only and punches into the tissue.

30 [005] The known methods of tissue incision include the use of scalpels and scissors that mechanically cut the target tissue. Scalpels and scissors are useful tools when the sharp edges of the devices are clearly in view of the clinician. However, during certain procedures the sharp edge or edges may be hidden

from view and prohibit the safe use of the cutting instrument. Furthermore, as the edges are hidden, it is very difficult to determine the precise depth of cut. Other methods of tissue manipulation include the dissection of different structures along natural lines by dividing or tearing the connective tissues. A blunt or sharpened obturator, such as those used with trocars, may also be used to cut and/or dissect tissue. Again, with these devices it is difficult to determine the precise depth of cut. Electrosurgery devices are commonly used to surgically separate tissue. Other means of tissue manipulation include the use of energy-assisted scalpels. These devices make use of ultrasonic, laser, and radio frequency energies to assist in the manipulation of tissues. Excess energy delivered by these devices can result in collateral tissue damage, such as thermal charring and desiccation. Therefore, what is needed is a system and method for cutting that will allow precise control of the cutting edge and for rapid cutting of various materials including incision or dissection of tissues in a more controlled manner than currently exists.

Summary of the Invention

[006] The present invention provides a means for rapid cutting of various materials including incision or dissection of tissues in a more controlled manner than currently exists. As an aspect of one exemplary embodiment of the invention, a blade and blade actuation mechanism is provided that allows for simultaneous rotation and advancement of a cutting edge. In one arrangement of the invention, the system of the present invention provides an appropriate blend of slicing and downward force in order to cut efficiently. In one exemplary arrangement, at least two such motions are combined when cutting, thereby enhancing the efficiency of a blade element in at least some applications.

[007] Another aspect of the invention, present in at least some embodiments, is to optimize the efficiency of the cutting action by providing, for a cut along a straight path, linear motion along two of the three principal axes which beneficially affect cutting performance (slicing and downward forces) and in addition provide beneficial torque about the lateral axis, while minimizing motion and torque which is not beneficial, such as linear motion along the lateral axis or

torque on the principal axes. It will be appreciated that, for a straight cut, linear motion relative to the longitudinal axis of the cutting element results in a slicing cut, and linear motion relative to the vertical axis results in a chopping or plunge cut. It will also be appreciated that a slicing motion is the result of torque.

[008] In another aspect of at least certain embodiments of the invention, a system of optimized load parameters is determined. The factors used in determining load parameters may include some or all of the: type of tissue to be incised, desired incision results including incision depth, curved or straight cutting edge, and curvilinear or straight cutting paths. The resultant optimized load parameters include, in at least certain embodiments: the resultant force vector; velocity and acceleration; and uniformity and/or consistency of load rates and velocity.

[009] Another aspect of at least some embodiments of the invention is the flexibility to use the cutting system as a tissue manipulator for blunt dissection, or as a tissue probe. Various housings, drive mechanisms and cutting element shapes are proposed, with the application impacting the particular implementation of each of these elements in each specific implementation.

Brief Description of the Figures

[010] Figures 1A-1B illustrate a cutting assembly in accordance with the present invention mounted at the distal tip of a pen-style housing, with Figure 1B further showing a front elevational view including an illumination source.

[011] Figures 2A-2B illustrate a cutting assembly in accordance with the present invention mounted on a handpiece.

[012] Figures 3A-3D illustrate various details of a first implementation of a cutting assembly in accordance with the invention.

[013] Figures 4A-4B illustrate the range of motion of a first implementation of a cutting assembly in accordance with the invention.

[014] Figures 5A-5B illustrate an alternative range of motion for a cutting assembly in accordance with the invention.

[015] Figures 6A-6D illustrate a further alternative range of motion for a cutting assembly in accordance with the invention.

- [016] Figures 7A-7D illustrate various details of a cutting assembly having a shark-fin style blade.
- [017] Figures 8A-8D illustrate various details of a cutting assembly having an elliptical style blade.
- [018] Figures 9A-9D illustrate various details of a cutting assembly having an advancing round blade.
- [019] Figures 10A-10D illustrate various details of a cutting assembly having a retreating bearing block.
- 10 [020] Figures 11A-11D illustrate a few of the many possible blade shapes usable with the cutting assembly of the present invention.
- [021] Figures 12A-12C illustrate a dual blade configuration.
- [022] Figures 13A-13B illustrate an implementation of a cutting assembly having monopolar and bipolar electrocautery, respectively.
- [023] Figure 14 illustrates a pinion gear drive assembly for actuating the blade.
- [024] Figure 15 illustrates a pulley drive assembly for actuating the blade.
- [025] Figure 16 illustrates a bevel gear drive assembly for actuating the blade.
- [026] Figure 17 illustrates a direct motor drive assembly for actuating the blade.
- 20 [027] Figure 18 illustrates a crank arm drive assembly for actuating the blade.
- [028] Figures 19A-19D illustrates an implementation of a cutting assembly having a cantilever spring element.
- [029] Figures 20 illustrates a detailed perspective view of the cutting assembly of Figures 19A-19D.

Detailed Description of the Invention

- 30 [030] Referring first to Figures 1A and 1B, a cutting assembly 100 may be mounted at the distal tip of a pen like housing 110. The cutting assembly 100 may be used for cutting various materials. As one example, not intended to be a limitation, the cutting assembly can be used to cut commercially manufactured materials, such as paper or plastic, as well as organic material, such as animal or human tissue. The cutting assembly 100 can be made in a variety of shapes,

but for the sake of clarity the cutting assembly 100 is shown to emulate the shape of a hand held cutting instrument, such as a scalpel. Furthermore, for the sake of clarity, the cutting assembly will be discussed or described herein in the context of cutting or manipulating organic tissue. However, the functional elements discussed and the methods set forth can easily be applied application relating to cutting manufactured materials, such as Kevlar or other fabrics.

[031] Considered in the context of cutting animal or human tissue, the cutting assembly 100 described herein requires less lateral tissue stabilization, thus allowing the user - for example, a clinician - to perform more precise curvilinear incisions. Furthermore, illumination elements, such as LED's 120, which are best seen in Figure 1B may be added to enhance the clinician's view of the target tissue. An activation button 130 is typically provided to actuate the cutting assembly 100 as described in greater detail hereinafter. The housing 110 may also contain batteries, appropriate connectors, and/or a power switch, and may be disposable or reusable, depending on the particular implementation.

[032] Referring next to Figures 2A and 2B, a cutting element assembly 200 in accordance with the present invention may alternatively be mounted at the distal tip 210 of an elongate cannula-like structure 220 that is connected to a hand piece 230, thus forming a tool 235 suitable for Laparoscopic surgical uses, as well as any other application in which a hand piece will simplify repositioning or operation of the cutting assembly 200. Additionally, an articulating mechanism 240 may be added proximally to the cutting element 200 to enhance user-directed positioning of the tool 235, which may in turn be adjusted by articulation control 250. A trigger or other actuator 260 is provided to actuate the cutting assembly 200. The trigger 260 could be implemented as a conventional trigger, a variable speed switch, an on/off pushbutton, or any other form of actuator. The housing could also include an internal working channel, a light, a scope or a camera, again chosen based on the particular implementation.

[033] As a still further alternative, the cutting element assembly 200 in accordance with the present invention may be mounted at the distal tip of an elongate cannula like structure 220 and connected to robotic assembly.

[034] Referring next to Figures 3A-3D, a first implementation of a cutting assembly 300 that incorporates at least some of the features of the invention can be better appreciated. Figure 3A illustrates in top plan view the distal end of a housing 310 and the cutting assembly 300. Figure 3B illustrates a front elevation view of the cutting assembly 300 including a rotary cutting blade 320. Figure 3C illustrates a side elevation view of the cutting assembly 300 and the housing 310 and Figure 3D illustrates a cut-away view showing the cutting blade 320 and the housing 310 along the line A-A in Figure 3A. The cutting assembly 300 includes a bearing block 330 that supports a bearing 340. An axle 350 passes through an eccentric bore in the cutting blade 320 and into the bearing 340, such that the bearing block 330 provides a low friction pivot for the cutting blade 320, provides protection from the cutting blade 320 when not actuated, and limits the amount of the cutting blade 320 that is exposed when actuated during a cutting event. Furthermore, the bearing block 330 aligns the cutting blade 320 along a desired cutting path, allows cutting motions only in beneficial directions and inhibits or prevents motion in non-beneficial directions. The degree of blade eccentricity, as defined by the location of the eccentric bore in the cutting blade 320, defines the depth of cut and the ratio of slicing motion to plunging motion.

[035] A separate external driver mechanism, discussed hereinafter in connection with Figures 14-18, is required to urge the blade about the pivot and to define the cutter velocity. A source of motive force, such as a motor and energy storage device, form part of the driver mechanism. The incision system of Figures 3A-3D operates as follows. For the sake of convenience only, a housing of the sort shown in Figure 1 will be assumed, although the particular form of housing is not limiting. A user initiated cutting event begins by actuating an activation switch, such as the activation switch 130 of Figure 1, which causes the driver mechanism to provide a resultant rotational movement of the cutting blade about the cutting blade pivot or axle. The cutting blade, such as the cutting blade 320 of Figures 3A-3D, has an eccentric bore and, hence is eccentrically mounted. Accordingly, upon rotation of the eccentrically mounted cutting blade

about the pivot, the cutting edge simultaneously advances and rotates into the target tissue.

[036] In one arrangement, the eccentrically mounted circular cutting blade is intermittently rotated at least one complete revolution as a means of cutting tissue. Many other cutting motions are possible, including reciprocating movement, partial rotation, continuous rotation, and intermittent rotation through less than a full revolution.

[037] As shown best in Figure 3D, in a first position, the eccentrically mounted cutting blade 320 is "parked" or rotated to a safe state where no part of the cutting blade 320 extends beyond a distal tip 370 of the bearing block 330 that in order to protect and prevent accidental contact with the cutting blade 320. In this position, clinicians and the patient are protected from the cutting blade 320 by the distal tip 370 of the bearing block 370. In this first position the cutting assembly 300 may used as a tissue manipulator for blunt dissection, or as a tissue probe.

[038] By rotating the cutting blade 320 about the axle 350, the eccentric mounting of the cutting blade 320 causes a portion of the cutting blade 320 to be exposed beyond the bearing block 330, thus allowing tissue to be cut. The exact amount of the cutting blade 320 that is exposed by such rotation is determined by the location of the eccentric bore in the cutting blade 320 relative to the blade center 380, and the extent to which the cutting blade 320 is rotated about the bearing block 330, which can be better appreciated from Figures 4A-4B.

[039] Figure 4A shows a side elevation view of the bearing block 330 and the cutting blade 320, and Figure 4B shows a cut-away view of the cutting blade 320 mounting relative to the bearing block 330. In the position shown in Figures 4A and 4B, the eccentric mounted cutting blade 320 reaches peak extension as limited by the degree of eccentricity. In this position, the maximum depth of a cut 410 is regulated and the cutting blade 320 has achieved maximum angular velocity along the principal cutting axis in a rotational direction 420.

[040] By continued rotation of the eccentrically mounted cutting blade 320, the cutting blade 320 returns to the safe or parked state as described above. In an

aspect of the invention implemented in some embodiments, the cutting blade is caused to automatically return to the parked position when the clinician or other user turns off the device by de-actuating the on/off switch, such as depressing the activation switch, or other actuator.

[041] As noted previously, the exact cutting motion may vary depending on the particular implementation and may, for example, comprise multiple uninterrupted rotations with the cutting blade starting and ending in the safe position or, as a further alternative, may comprise reciprocal rotation about the pivot as a means of cutting tissue.

10 [042] Referring next to Figures 6A-6D, an embodiment wherein a blade 600 that is capable of reciprocating motion is shown, where Figure 6A is a side elevation view of a bearing block 610 and the blade 600, Figure 6B shows one exemplary rotation about a bearing or pivot 620, Figure 6C shows the blade at maximum exposure, and Figure 6D is a cut-away view showing a drive shaft 630 affixed to the blade 600 to cause the reciprocating motion about the pivot 620. Again the amount of blade exposed is determined by the degree of eccentricity in the mounting, or the position of the pivot 620 relative to the blade center 640.

20 [043] In another alternative implementation, shown in Figures 7A-7D, a housing 700 shown in side elevation view in Figure 7A and 7B and cut-away side views in Figures 7C and 7D a concentrically mounted cutting blade 710 having at least one protruding or "shark-fin" style blade element 720 is intermittently or continuously rotated a fractional revolution, a complete revolution or a multiplicity of revolutions as a means of cutting tissue. As shown in Figure 7B, the cutting blade 710 is contained within the housing 700 while the blade element 720 is exposed. The blade element 720 may be constructed in a manner to provide a cam like cutting edge with increasing blade engagement as the blade element 720 advances, until the blade element 720 reaches maximum exposure and maximum velocity in a rotational direction 730 as shown in Figure 7D.

30 [044] As an alternative to the "shark-fin" style blade element 720, the cutting blade 710 may have an elliptical shape as shown in Figures 8A-8D or any other non-circular shape, including rectangular, triangular, trapezoidal, and so on, such

that the blade has a tip portion as a cutting surface which serves to intermittently contact the tissue during rotation.

[045] In a still further alternative implementation shown in Figures 9A-9D, a concentrically mounted circular blade 900 is intermittently or continuously rotated about a moveable pivot 910 housed within a protective bearing block 920. A clinician initiated cutting event is actuated by means of an energy storing mechanism 930 that provides a resultant rotational moment about the pivot 910 and a simultaneous advancement of the pivot 910 within the protective bearing block 920.

10 [046] Alternatively, as shown in Figures 10A-10D, a protective bearing block 1000 is configured to retreat relative to a blade 1010 when a driver mechanism 1030 is actuated, thus exposing the blade 1010 to the tissue.

[047] In either case, the blade rotation mechanism will be an independent element (such as a drive shaft with pinion gear, bearing element, and enclosure) that is able to move longitudinally relative to a shaft within a blade protection housing. In such an arrangement, the bearing block and protective housing may be divided, if desired, and either the blade would be moved forward or the housing moved back. Optionally, the blade may be serrated to enhance cutting specific tissues, and a few of the many examples of available blade designs suitable for use with the present invention are shown in Figures 11A-11D.

20 [048] In another implementation shown in Figures 12A-12C, more than one blade, such as blades 1210 and 1220, may be utilized. The blades are mounted parallel to one another and may be used to make parallel incisions or strips of tissues. Furthermore, blades may be mounted synchronously or asynchronously with respect to the axle; that is, if synchronous, the two blades rotate or advance together, and if asynchronous, the two blades move independently (at different times or rates, for example) relative to one another.

[049] Additionally, as shown in Figures 13A-13B, mono-polar or bi-polar electrocautery may be added for further tissue manipulations. Thus, in Figure 30 13A, showing a monopolar electrocautery arrangement, a blade 1300 is polarized with a first polarity (for example, positive) relative to a housing 1310. Or, as

shown in the bipolar arrangement of Figure 13B, insulators 1320 may be mounted on either side of the blade 1300 and within the housing 1310 such that the blade 1300 has a first polarity and closely juxtaposed contacts 1330 are maintained at the opposite polarity,

[050] Referring next to Figures 14-18, many different means of power transmission may be employed to drive the cutting elements. The cutting elements may be driven in a rotary or oscillating mode depending on the clinical application. For example, as shown in Figure 14, an arrangement of a pinion gear 1410 and shaft 1420 may be used with the blade 1430 notched concentrically about the axle 1440. Or, as shown in Figure 15, a drive belt, chain or cable 1500 mounted on an input pulley 1510 and a drive pulley 1520 connected to a blade 1530 and an axle 1540 may also be used to transmit power to the blade 1530, where a drive mechanism such as a motor, air turbine or other source of motive force is connected to the axle of the input pulley 1510.

[051] As shown in Figure 16, a rotating shaft 1600 mounted perpendicular to an axle 1610 and a blade 1620 may also be used in conjunction with a variety of well known mechanisms such as bevel gears, crown gear sets or spatial revolute-cylindrical- cylindrical-revolute couplings 1630A-B to drive the blade.

[052] As shown in Figure 17, a motor 1700 may be directly connected to an axle 1710 and electronically controlled. Or, as shown in Figure 18, reciprocating motion to a cutting element may also be achieved through the use of a slider crank type mechanism 1800 connected to a cam arm 1810 at a blade pivot axle 1820. Alternatively, by mounting the crank 1800 on the outside of the cam arm 1810, full rotation may be achieved. Optionally, the cutting element may also be driven by hydraulic or pneumatic means.

[053] Referring next to Figures 19A-19D and Figure 20, a cutting assembly 1900 is shown having a shaft 1910, a blade 1920, and a housing 1930 with a cavity located at the end of the housing 1930 proximate to the blade 1920. A cantilever spring element 1912 is located at one end of the shaft 1910. The spring element 1912 is located proximate to and in contact with a central axle 1922 of the blade 1920 as shown in Figures 19A-D and Figure 20. The central

axle 1922 is positioned within the cavity of the housing 1930, such that the forward motion the blade 1920, which is cause by the linear motion of the shaft 1910, is limited as seen in cross-section view of Figure 19D taken along the line C-C of Figure 19C. When the central axle 1922 has reached the maximum linear travel in a direction 1950, the blade 1920 is extended the maximum distance out from the housing 1930 as shown in Figure 19B. However, the shaft 1910 can continue its linear travel in the direction 1950. Accordingly, this linear travel of the shaft 1910 is translated into rotational motion 1960 of the blade 1920 as the shaft 1910 forces a pin 1924, which is secured to the blade 1920, to rotate about the axle 1922 until the spring element 1912 is compressed and the maximum linear motion of the shaft 1910 is reached as shown in Figure 19C. Consequently, the rotation of the pin 1924 about the axle 1922 results in the rotational motion 1960 of the blade 1920. Thus, the linear motion 1950 of the shaft 1910 first results in extension of the blade 1920 from the housing 1930 and then rotational motion 1960 of the blade 1920 about the axle 1922.

[054] Mounting of the cutting element assembly is generally application specific. However, it is important to note that certain configurations may be useful for multiple applications.

[055] It will thus be appreciated that a new and novel design of incision system has been disclosed. Among the advantages offered by one or more of implementations of the invention are a controlled depth of cut, a retractable blade offering increasing user and patient safety, high relative velocity of cutting element permitting lower cutting forces applied by the user, and flexible mounting arrangements including articulated and more conventional mountings. Having fully disclosed a variety of implementations of the present invention, it will be appreciated by those skilled in the art that numerous alternatives and equivalents exist which do not materially alter the invention described herein. Therefore, the invention is not intended to be limited by the foregoing description, but instead only by the appended claims.